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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/335,296	11/07/94	YAMAMOTO J	2307U2377

EXAMINER
MINNIFIELD

18N1/0418

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ART UNIT	PAPER NUMBER
1813	2

DATE MAILED: 04/18/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-3 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-3 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

15. The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. See for example p. 21 of the specification. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

16. The disclosure is objected to because of the following informalities: p. 14, l. 7-8, "d eposited" should be --deposited--; p. 30, l. 7, is it µm or µg; p. 36, l. 32, "µ", is it µg or µl; and there may be others. Appropriate correction is required.

17. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5275813. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to a vaccine against FIV infection and methods of protection.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37

C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

18. Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited vaccines comprising immunogens that provide immunological protection against FIV. The claims recite vaccine comprising an immunogen which broadly interpreted could include any component or antigen. The immunogen could also include any component of the FIV, whole virus, subunits of the virus, polypeptides of the virus (natural or synthetic), envelope proteins, and inactivated proteins, however the specification (p. 43) discloses that the envelope protein is essential for immunological protection however the specific viral protein and specific immune responses which provide such protection are uncertain. See M.P.E.P. §§ 706.03(n) and 706.03(z).

19. Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim lacks positive antecedent basis because the claim recites a "vaccine composition", however claim 1 does not refer to a " vaccine composition.

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

23. This application repeats a substantial portion of application Serial No. 08/226447, filed April 12, 1994, and adds and claims additional disclosure not presented in the prior application. The application now refers to the FTLV as FIV which constitutes new matter. Applicants parent application, 07/089700

and 08/226447 disclose a vaccination with FTLV, the whole virus, against FTLV. However, kittens 2428 and 2429 were given experimental vaccine (whole FTLV) as well as a broad spectrum of antibiotic therapy. The infection and fever disappeared after antibiotic treatment, therefore it is unclear if the experimental vaccine caused the "improvement". Further, the inactivation method of the virus in the preparation of the vaccine is not the same. Application 08/226447 (p. 20) describes the use of psoralen and formaldehyde to inactivate the virus however, the present application (p. 30) uses paraformaldehyde for inactivation of the virus. Even if Examiner concedes that paraformaldehyde and formaldehyde are the same, the concentrations used are not the same, 0.8% vs 1.25%, and the present application does not use psoralen in the inactivation method. It is unclear if the differences in the concentration and compounds would yield the same level of inactivated virus for the vaccine preparation, and that the vaccine would have the same level of effectiveness, protection. Therefore, present application has been examined as of the filing date of November 7, 1994.

24. Claims 1-3 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Pedersen et al. ('753 or '602), Hohdatsu et al., or Yamamoto et al..

Pedersen et al. ('753 or '602) disclose a vaccine comprising FIV, whole and partially inactivated virus and subunits, to immunize against FIV infection, also commonly known as FTLV (abstract; examples). Hohdatsu et al. disclose cats passively immunized with sera from FIV vaccinated cats or cats infected with FIV were protected from FIV infection (abstract; pp. 2344-

2348; table 2). Yamamoto et al. disclose that cats immunized with inactivated whole infected-cell or cell-free FIV vaccines were protected against FIV infection in cats and the use of adjuvants in the vaccine composition (abstract; pp. 601-605).

The prior art, Pedersen et al. ('753 or '602), Hohdatsu et al., or Yamamoto et al., discloses a vaccine and methods for protecting a cat against FIV infection which appears to be the same as the claimed invention because, they disclose protection against FIV infection after challenge with FIV. The claims recite a vaccine comprising an immunogen capable of eliciting an immune response protective against infection by FIV; the immunogen can comprise any component of the FIV (subunits of FIV, inactivated virus, partial or whole virus, specific proteins of FIV, or sera from animals vaccinated with FIV). Therefore, the prior art vaccine and methods for protecting cats against FIV infection appear to be the same, with any other identifying characteristics inherent in them.

And if the prior art vaccine and methods for protecting a cat against FIV infection are not the same as that claimed, they are obvious variations of that claimed, which the teachings of the prior art would have reasonably suggested to one of ordinary skill in the art at the time the invention was made, the vaccine and methods for protecting a cat against FIV infection, making the claimed invention, as a whole prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Since the Office does not have the facilities for examining and comparing applicants' vaccine and methods for protecting a cat against FIV infection and the vaccine and methods for protecting a cat against FIV infection of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed vaccine and methods for protecting a cat against FIV infection and the vaccine and methods for protecting

a cat against FIV infection of the prior art (i.e., that the vaccine and methods for protecting a cat against FIV infection of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine and methods for protecting a cat against FIV infection). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

25. No claims are allowed.

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine M. Nucker, can be reached on (703) 308-4028. The fax phone number for this Group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

HAZEL F. SIDBERRY
PRIMARY EXAMINER
GROUP 1800

N. M. Minnifield
April 7, 1995